

AMENDMENTS

In the claims:

Please cancel claims 55, 72, 87, 102 and 124.

Please replace claims 46-54, 56-71, 73-86, 88-101, 103-123 and 125-136 with the following clean set of claims.

46. (Amended) A nucleic acid/lipid/polycationic polypeptide salt complex comprising a nucleic acid, at least one lipid species, and at least one polycationic polypeptide salt, wherein the complex has a net neutral or a net negative charge.

47. The complex of claim 46, wherein the complex has a net neutral charge.

48. The complex of claim 46, wherein the complex has a net negative charge.

49. (Amended) The complex of claim 46 wherein, in the at least one polycationic polypeptide salt, arginine residues constitute at least about 30 % of the amino acid residues, and lysine residues constitute less than about 5 % of the amino acid residues of the polypeptide.

50. The complex of claim 46, wherein the complex comprises a positively charged surface.

51. (Amended) The complex of claim 46 wherein, in the at least one polycationic polypeptide, arginine residues constitute about 65 to 75 % of the amino acid residues, and lysine residues constitute about 0 to 3% of the amino acid residues of the polypeptide.

52. (Amended) The complex of claim 46, wherein the at least one polycationic polypeptide salt is a sulfate salt.

53. (Amended) The complex of claim 46, wherein the at least one polycationic polypeptide salt comprises an ion having two negative charges.

54. (Amended) The complex of claim 46, wherein the at least one polycationic polypeptide salt is a protamine sulfate.

56. (Amended) The complex of claim 46, wherein the nucleic acid comprises an E1A gene.

57. (Amended) The complex of claim 46, wherein the at least one lipid is a cationic lipid.

58. (Amended) The complex of claim 46, wherein the at least one lipid is 3β[N-(N', N'-dimethylaminoethane)-carbonyl]cholesterol (DC-Chol).

59. (Amended) The complex of claim 46, wherein the at least one polypeptide is from about 20 to about 100 amino acids in length.

60. The complex of claim 46, wherein the complex further comprises a neutral phospholipid species.

61. (Amended) The complex of claim 46, wherein the ratio of the nucleic acid:lipid:polycationic polypeptide salt is about 1 μg/0.1 nmol/0.01 μg to about 1 μg/200 nmol/100 μg.

62. The complex of claim 46, wherein the complex has a diameter of less than about 400 nm.

63. The complex of claim 46, wherein the complex is shielded.

64. The complex of claim 46, further comprising a compound comprising polyethylene glycol moieties.

65. The complex of claim 50, wherein the complex is shielded.

66. The complex of claim 65, wherein the complex comprises a compound comprising polyethylene glycol moieties.

67. The complex of claim 46, further comprising a lipophilic surfactant.

68. (Amended) A method for producing a nucleic acid/lipid/polycationic polypeptide salt complex of claim 46, the method comprising combining the nucleic acid, the at least one lipid and the at least one polycationic polypeptide salt to form the complex.

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69. (Amended) The method of claim 68, wherein the nucleic acid, lipid and polycationic polypeptide salt are mixed in a ratio of about 1 µg/0.1 nmol/0.01 µg to 1 µg/200 nmol/100 µg.

70. (Amended) The method of claim 68, wherein the at least one lipid is a cationic lipid.

71. (Amended) The method of claim 70, wherein the at least one cationic lipid is 3β[N-(N', N'-dimethylaminoethane)-carbamoyl]cholesterol (DC-Chol).

73. (Amended) The method of claim 69, wherein the at least one polycationic polypeptide salt is a protamine sulfate.

74. (Amended) A method for delivering nucleic acid to cells comprising contacting the cells with the complex of claim 46.

75. (Amended) The method of claim 74, wherein the cells are contacted with the complex *in vivo*, the method comprising administering the complex to an animal or human in an amount effective to deliver the nucleic acid into the cells of the animal or the human.

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76. (Amended) The method of claim 74, wherein the at least one lipid is 3β[N-(N', N'-dimethylaminoethane)-carbamoyl]cholesterol (DC-Chol), and the at least one polycationic polypeptide salt is a protamine sulfate.

77. (Amended) A nucleic acid/lipid/polycationic polypeptide salt complex comprising a nucleic acid, at least one lipid species, and at least one polycationic polypeptide salt, wherein the complex further comprises a targeting factor.

78. (Amended) The complex of claim 77, comprising a nucleic acid, at least one lipid species, and at least one polycationic polypeptide salt in a ratio such that the complex has a positive charge excess of lipid and polycationic polypeptide salt to nucleic acid.

79. The complex of claim 77, wherein the complex has a net neutral or ~~net~~ negative charge.

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80. (Amended) The complex of claim 77 wherein, in the at least one polycationic polypeptide salt, arginine residues constitute at least about 30 % of the amino acid residues, and lysine residues constitute less than about 5 % of the amino acid residues of the polypeptide.

81. (Amended) The complex of claim 77 wherein, in the at least one polycationic polypeptide, arginine residues constitute about 65 to 75 % of the amino acid residues, and lysine residues constitute about 0 to 3% of the amino acid residues of the polypeptide.

82. The complex of claim 81, wherein the complex has a net positive charge.

83. The complex of claim 81, wherein the complex has a net neutral or net negative charge.

84. (Amended) The complex of claim 77, wherein the at least one polycationic polypeptide salt is a sulfate salt.

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85. (Amended) The complex of claim 77, wherein the at least one polycationic polypeptide salt comprises an ion having two negative charges.

86. (Amended) The complex of claim 77, wherein the at least one polycationic polypeptide salt is a protamine sulfate.

88. (Amended) The complex of claim 77, wherein the nucleic acid comprises an E1A gene.

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89. (Amended) The complex of claim 77, wherein the at least one lipid is a cationic lipid.

90. (Amended) The complex of claim 77, wherein the at least one lipid is 3β[N-(N', N'-dimethylaminoethane)-carbamoyl]cholesterol (DC-Chol).

91. (Amended) The complex of claim 77, wherein the at least one polypeptide is from about 20 to about 100 amino acids in length.

92. The complex of claim 77, wherein the complex further comprises a neutral phospholipid species.

93. (Amended) The complex of claim 77, wherein the ratio of the nucleic acid:lipid:polycationic polypeptide salt is about 1 µg/0.1 nmol/0.01 µg to about 1 µg/200 nmol/100 µg.

94. The complex of claim 77, wherein the complex has a diameter of less than about 400 nm.

95. The complex of claim 77, wherein the complex is shielded.

96. The complex of claim 77, further comprising a lipophilic surfactant.

97. The complex of claim 77, further comprising a compound comprising polyethylene glycol moieties.

98. (Amended) A method for producing a nucleic acid/lipid/polycationic polypeptide salt complex of claim 77, the method comprising combining the nucleic acid, the lipid, the polycationic polypeptide salt, and the targeting factor to form the complex.

99. (Amended) The method of claim 98, wherein the nucleic acid, lipid and polycationic polypeptide salt are mixed in a ratio of about 1 µg/0.1 nmol/0.01 µg to 1 µg/200 nmol/100 µg.

100. (Amended) The method of claim 98, wherein the at least one lipid is a cationic lipid.

101. (Amended) The method of claim 100, wherein the at least one cationic lipid is 3β[N-(N', N'-dimethylaminoethane)-carbamoyl]cholesterol (DC-Chol).

103. (Amended) The method of claim 98, wherein the at least one polycationic polypeptide salt is a protamine sulfate.

104. (Amended) A method for delivering nucleic acid to cells comprising contacting the cells with the complex of claim 77.

105. (Amended) The method of claim 104, wherein the cells are contacted with the complex *in vivo*, the method comprising administering the complex to an animal or human in an amount effective to deliver the nucleic acid into the cells of the animal or the human.

106. (Amended) The method of claim 105, wherein the at least one lipid is 3β[N-(N', N'-dimethylaminoethane)-carbamoyl]cholesterol (DC-Chol), and the at least one polycationic polypeptide salt is a protamine sulfate.

107. The complex of claim 77, wherein the targeting factor is selected from the group consisting of modified lipids, proteins, polycations and receptor ligands.

108. The complex of claim 77, wherein the targeting factor is selected from the group consisting of asialoglycoprotein, insulin, low density lipoprotein (LDL), folate, monoclonal antibodies and polyclonal antibodies.

109. The complex of claim 77, wherein the targeting factor is directed to a cell type selected from the group consisting of liver, blood, endothelial and tumor cells.

110. The complex of claim 81, wherein the targeting factor is selected from the group consisting of modified lipids, proteins, polycations and receptor ligands.

111. The complex of claim 81, wherein the targeting factor is selected from the group consisting of asialoglycoprotein, insulin, low density lipoprotein (LDL), folate, monoclonal antibodies and polyclonal antibodies.

112. The complex of claim 81, wherein the targeting factor is directed to a cell type selected from the group consisting of liver, blood, endothelial and tumor cells.

113. (Amended) A method of administering a nucleic acid to a human or animal, the method comprising administering to the human or animal a nucleic acid/lipid/polycationic polypeptide salt complex comprising a nucleic acid, at least one lipid species, and at least one polycationic polypeptide salt, wherein the complex is administered intratumorally, intravenously, intratracheally, intraperitoneally or intramuscularly.

114. The method of claim 113, wherein the complex is administered intravenously.

115. ~~The method of claim 113, wherein the complex is administered as an aerosol or liquid solution.~~

116. (Amended) The method of claim 113, wherein the complex comprises a nucleic acid, at least one lipid species, and at least one polycationic polypeptide salt in a ratio such that the complex has a positive charge excess of lipid and polycationic polypeptide to nucleic acid.

117. The method of claim 113, wherein the complex has a net neutral or net negative charge.

118. (Amended) The method of claim 113, wherein, in the at least one polycationic polypeptide salt, arginine residues constitute at least about 30 % of the amino acid residues, and lysine residues constitute less than about 5 % of the amino acid residues of the polypeptide.

119. (Amended) The method of claim 113 wherein, in the at least one polycationic polypeptide, arginine residues constitute about 65 to 75 % of the amino acid residues, and lysine residues constitute about 0 to 3% of the amino acid residues of the polypeptide.

120. The method of claim 119, wherein the complex has a net positive charge.

121. ~~The method of claim 119, wherein the complex has a net neutral or net negative charge.~~

122. (Amended) The method of claim 113, wherein the at least one polycationic polypeptide salt is a sulfate salt.

123. (Amended) The method of claim 113, wherein the at least one polycationic polypeptide salt is a protamine sulfate.

125. (Amended) The method of claim 113, wherein the nucleic acid comprises an E1A gene.

126. (Amended) The method of claim 113, wherein the at least one lipid is a cationic lipid.

127. (Amended) The method of claim 113, wherein the at least one lipid is 3 β [N-(N', N'-dimethylaminoethane)-carbamoyl]cholesterol (DC-Chol).

128. (Amended) The method of claim 113, wherein the at least one polypeptide is from about 20 to about 100 amino acids in length.

129. The method of claim 113, wherein the complex further comprises a neutral phospholipid species.

130. The method of claim 113, wherein the complex has a diameter of less than about 400 nm.

131. The method of claim 113, wherein the complex is shielded.

132. The method of claim 113, wherein the complex further comprises a lipophilic surfactant.

133. The method of claim 113, wherein the complex further comprises a compound comprising polyethylene glycol moieties.

134. (Amended) The method of claim 113, wherein the nucleic acid, lipid and polycationic polypeptide salt are present in a ratio of about 1 μ g/0.1 nmol/0.01 μ g to 1 μ g/200 nmol/100 μ g.

135. (Amended) The method of claim 113, comprising administering the complex to an animal or human in an amount effective to deliver the nucleic acid into cells of the animal or the human.

136. The method of claim 113, wherein the complex further comprises a targeting factor.